K093567 (1/2)

3. 510(K) SUMMARY

Applicant / Sponsor:	ANOVA Implant Solutions, LLC Two Maryland Farms, Suite 120 Brentwood, TN 37027 FEB - 5 2010
Contact Person:	Walter Spires Tel: (615) 457-3311 Fax: (615) 457-3312
Proprietary Name:	Active Knee Total Knee Replacement System
Common Name:	Total Knee Replacement System
Classification Name:	21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis, Class II
Product Codes:	JWH
Substantially Equivalent Devices:	Active Knee Total Knee Replacement System (K021740)

Device Description:

The Active Knee System is a modular knee system consisting of a femoral component, a meniscal (tibial) insert, a tibial base plate implant and a patella. The tibial base plates and patella components included in this submission have been previously cleared in K021740. The femoral components are a design iteration of the femoral components cleared in K021740. The Ultracongruent Plus tibial inserts included in this submission are similar to the Ultracongruent tibial inserts previously cleared in K021740 but are designed with a higher anterior lip for use in patients with an absent or severely deficient posterior cruciate ligament.

The Active Knee System femoral components are manufactured from Co-Cr-Mo alloy conforming to ASTM F75 and are available in sizes 1 - 5. Sizes 2, 3, 4, and 5 are also available in a narrow version. The femoral components are asymmetric and are available in right and left versions.

The Active Knee System tibial base plates are manufactured from Co-Cr-Mo alloy conforming to ASTM F75 and are available in sizes 1-5. All sizes are available in narrow and wide versions.

The Active Knee System Ultracongruent Plus tibial inserts are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPe) conforming to ASTM F648 and are available in sizes 1 – 5. Sizes 2, 3 4, and 5 are also available in narrow versions. The tibial inserts are available in thicknesses ranging from of 6.0 to 17.5mm.

The Active Knee System patella implants are manufactured from UHMWPe conforming to ASTM F648 and are available in sizes 1 – 5.

Intended Use / Indications:

The Active Knee Total Knee Replacement System is indicated to be used only with bone cement in patients suffering from the following conditions:

- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis.
- Inflammatory degenerative joint disease including rheumatoid arthritis.
- Correction of functional deformity such as varus, valgus, or flexion deformities.
- Revision procedures where other treatments or devices have failed.
- Treatment of fractures that are unmanageable using other techniques.

The device is intended for single use only.

Summary of Technologies/Substantial Equivalence:

The Active Knee Total Knee Replacement System with Ultracongruent Plus tibial inserts has the same indications, is offered in the same range of sizes and is manufactured from the same materials as the previously cleared Active Knee Total Knee Replacement System. The femoral components, tibial baseplates and patella implants are similar or identical to the previously cleared components. The Ultracongruent Plus tibial inserts are a design modification of the previously cleared Ultracongruent tibial inserts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

ANOVA Implant Solutions, LLC
% Mr. Walter Spires
Two Maryland Farms, Suite 120
Brentwood, Tennessee 37027

FEB - 5 2010

Re: K093567
Trade/Device Name: Active Knee Total Knee Replacement System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prothesis
Regulatory Class: II
Product Code: JWH
Dated: January 21, 2010
Received: January 27, 2010

Dear Mr. Spires:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K093567

Device Name: Active Knee Total Knee Replacement System

Indications for Use:

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- Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis.
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- Treatment of fractures that are unmanageable using other techniques.

The device is intended for single use only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093567